daily dosage unit, at least 200 µg folic acid, at least 1.9 µg vitamin B12 and at least 0.3 mg vitamin B6, and at least one component selected form the group consisting of riboflavin, thiamine, niacin and zinc.

--34. (new) The method of claim 33, in which the supplement composition contains at least 300 µg of folic acid, at least 4.8 µg of vitamin B12 and at least 3.0 mg of vitamin B6 per daily dosage.--

REMARKS

The application has been amended and is believed to be in condition for allowance.

Previously, claims 16-31 were pending, with claims 16 and 29 being independent. This amendment cancels claims 16-17, 20, and 26-27. New independent claim 31 replaces claims 16-17 and includes recitations found in canceled claim 20. New independent claim 33 replaces canceled claims 26-27.

New dependent claim 32 and dependent claim 34 include recitations based on those previously found in claim 29 and the disclosure of at least specification page 6, lines 28-29.

The Official Action rejected claims 16-30 under §112, first paragraph, as containing subject matter not described in the specification so as to reasonably convey to one of skill in the art that applicants had possession of the claimed invention.

The Official Action also rejected claims 16-30 under §112, second paragraph, as being indefinite.

In canceling some of the previously pending claims, amending others, and redrafting the independent claims, applicants believe that they have remedied the stated basis of both the §112, first and second paragraph rejections. Accordingly, reconsideration and withdrawal of these rejections are respectfully requested.

As to the enablement objections, applicants believe that the specification of amounts of the essential vitamins in all the claims overcome these objections. Note that the two new independent claims are for the administration of a complete food and food supplement, respectively. In the complete food claim 31, there has been incorporated the minimum amounts of previous claim 20 and have added the corresponding maximum amounts of Table 1 (specification page 8). In this claim, it has been furthermore clarified that the 100 kcal basis relates to the carbohydrates, fats and proteins of the complete food.

Furthermore, applicants believe that it is clear that these amended claims do not reflect undue experimentation and that the specification certainly gives sufficient direction as to any experimentation that may be necessary. Given that the invention has been disclosed so as to teach one of skill in the art how to make and use the invention, without undue

experimentation, the statutory requirement is believed to be clearly met.

As to the indefiniteness objections, the objected-to recitations have been amended so as to remedy the stated basis of objection.

Accordingly, the presently-pending claims are believed to be proper as to form and are believed to fully meet all the statutory requirements.

The Official Action rejected claims 16-28 under §103 as obvious over SERFONTEIN 5,631,271 in view of PAUL et al. 5,292,538.

The Official Action rejected claims 29 and 30 under §103 as obvious over SERFONTEIN alone.

Applicants have carefully studied each of these references and believe that the obviousness rejections are not well founded. Accordingly, reconsideration and withdrawal of the obviousness rejections and allowance of the pending claims are respectfully requested.

Concerning the prior art, SERFONTEIN is concerned with treating problems in the conversion of pyridoxine (the common vitamin B6 precursor) to pyridoxal (the active form of vitamin B6). However, disturbance of the pyridoxine-pyridoxal pathway, is totally unrelated to melatonin- or serotonin (table at the top of column 12)-mediated disorders.

Although the broad ranges of SERFONTEIN show some overlap with the presently claimed ranges, the preferred amounts and even stronger the more preferred and exemplified amounts of SERFONTEIN are distinctly lower than those of the present claims. See e.g. the preferred amount of folate of 0.01-0.2 mg per day (=10-200 µg per day) vs. the at least 200 µg of present claims 30 and 33 and 300 µg of claim 32. Assuming a minimum daily intake of 1000 kcal, the minimum amount of folic acid according to present claim 31 is more than 440 µg, i.e., well above even the broadly preferred amount of SERFONTEIN. The same is true for the other vitamins B6 and B12.

SERFONTEIN teaches to administer vitamin B6, and also vitamin B12 and folic acid. The administration of B6 is said to result in lowering homocysteine levels, which are the starting point of the problems caused by the insufficient pyridoxine-pyridoxal conversion. There is no relationship, certainly no known relationship, between homocysteine levels and senses of well being, the latter being the subject of the present invention. Moreover, the homocysteine metabolism is known to be largely concentrated in the liver. In contrast, serotonin- and melatonin-mediated effects are controlled by the metabolism of these components in the brains. This emphasizes the lack of relation between the two mechanisms. Thus, there is no motivation from SERFONTEIN to use the vitamins described by him

in a completely different condition, which was found furthermore to require much higher levels of the three vitamins.

PAUL et al. teaches the administration of a blend of sugars and proteins together with magnesium for anabolic use. Such use is related to physical conditions such as muscle catabolism and negative energy balance (see column 1, lines 15-26). These conditions are also unrelated to melatonin- and serotonin-mediated disorders. A broad vitamin mixture is suggested by PAUL et al. as well, including folic acid, vitamins B6 and B12 but only "to supplement and optimize the formulations for purposes of sustained energy and metabolism" (column 7, lines 44-48). This does not lead the skilled person in the direction of melatonin- or serotonin-mediated disorders. Also, the amounts of the specific vitamins as described by PAUL et al. are low, compared to the present invention.

Neither of SERFONTEIN and PAUL et al. refer to conditions that are relevant in the present claims. Therefore, there is no teaching to use their compositions for the recited purpose. Further, absent relevant teachings, there is no motivation to combine the two teachings.

In the paragraph bridging pages 8 and 9 of the Official Action, it seems that the argument is that a particular known use of a member of a class of materials (here: vitamins) would make the use of other members from the class obvious, regardless of the effect. However, there is no basis in vitamin science for

the suggestion that one vitamin can be randomly replaced by another one: each vitamin has its own specific target of action, which cannot be replaced by another vitamin. Accordingly, this stated basis for combining the references is not believed to be viable.

A review of these two references, taken either individually or in any reasonable combination, does not teach or suggest a method of treating or preventing the recited disorders. Nor is there taught or suggested a suitable pharmaceutical composition for the treatment or prevention of the recited disorders. In view of this, the obviousness rejections are not believed to be viable and it is respectfully requested that they be withdrawn.

Allowance of all the pending claims is respectfully requested.

Attached hereto is a marked-up version showing the changes made to the claims. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,

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"VERSION WITH MARKINGS TO SHOW CHANGES MADE"

IN THE CLAIMS:

Claim 18 has been amended as follows:

--18. (amended) The method according to claim [17] 31, in which the composition is a composition for complete nutrition of infants.--

Claim 19 has been amended as follows:

--19. (amended) The method according to claim [17] 31, in which the composition is a composition for complete nutrition of diseased or elderly persons.--

Claim 21 has been amended as follows:

--21. (amended) The method according to claim [17] 31, in which the composition further contains at least 0.55 mg of niacin and/or at least 0.08 mg of riboflavin and/or at least 55 µg of thiamine per 100 kcal.--

Claim 22 has been amended as follows:

--22. (amended) The method according to claim [17] 31, in which the composition further contains more than 50 mg of choline or betaine or the sum thereof, and/or at least 5 mg of taurine, and/or at least 50 mg of methionine per 100 kcal.--

Claim 23 has been amended as follows:

--23. (amended) The method according to claim [17] 31, in which the composition further contains 0.05-8 g of tryptophan

and/or 30-3000 mg of melatonin and/or 50-1000 mg of adenosine per 100 kcal.—-

Claim 24 has been amended as follows:

--24. (amended) The method according to claim [17] 31, in which the composition further contains 5-400 mg magnesium and/or 0.7-100 mg zinc per 100 kcal, and calcium, and having a [the] weight ratio of magnesium plus zinc to calcium [being] of higher than 0.08.—-

Claim 25 has been amended as follows:

--25. (amended) The method according to claim [17] 31, in which the composition contains 9-15 g of carbohydrates per 100 kcal.—-

Claim 28 has been amended as follows:

--28. (amended) The method according to claim [27] 33, in which the supplement further contains per daily dosage unit, at least 0.5 mg riboflavin and/or at least 1.0 mg thiamine and/or at least 2 mg niacin and/or at least 0.3 g tryptophan, at least 0.5 g melatonin, at least 50 mg adenosin, at least 50 mg choline and/or betaine and/or at least 100 mg methionine and/or at least 0.03 mg vitamin K and at least 5 g of digestible carbohydrates.—-

Claim 29 has been amended as follows:

--29. (amended) A pharmaceutical composition suitable for the treatment or prevention of serotonin- or melatonin-

mediated disorders, [such as improving senses of well being, control of feeling of pain and improvement of mood and sleeping behaviour,] the composition comprising carbohydrates, fats and proteins, and containing more than 44 µg up to 4000 µg of folic acid, more than 0.8 µg up to 2000 µg of vitamin B12 and more than 50 ug up to 10,000 µg of vitamin B6 per 100 kcal of said carbohydrates, fats and proteins, and further containing at least one of riboflavin, thiamine, niacin and zinc.--

Claim 30 has been amended as follows:

--30. (amended) The method of claim [16] 31, comprising administering an amount of at least 200 µg of folic acid, at least 2 µg of vitamin B12 and at least 2 mg of vitamin B6 per daily dosage[, together with at least one of riboflavin, thiamine, niacin and zinc].--